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EXAMINER	
STOUT, MICHAEL C	

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3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/553,745	POMFRETT ET AL.
	Examiner	**Art Unit**
	MICHAEL C. STOUT	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/06/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *24,25 and 43* is/are allowed.

6)☒ Claim(s) *22,23,26-42 and 44-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This detailed action is in regards to United States Patent Application 10/553,745 filed on 10/18/2005.

The Final Office action dated 4/26/2011 is hereby withdrawn by the Examiner.

The following Final Action is provided to replace the previous office action in order to correct formalities in the previous office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-26, 28, 33, 36, 38-40, 42 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boone (US 5,919, 142) In view of John et al. (US 2004/0079372 A1, hereinafter referred to as John '372) and John et al. (US 2002/0091335, hereinafter referred to as John '335).

Regarding claim 22, 38, and 42 Boone discloses a method for monitoring the response of a nervous system of a body to a sensory stimulus (abstract), said method comprising:

Boone teaches providing plurality of electrodes on a surface of the body, (multiple electrodes E1-E16 are placed around the subjects head) wherein current is passed between selected areas of the surface of the body by passing current between at least one pair of electrodes of said plurality (current from the current generator is passed between E11 and E12, see Column 4, Lines 7-10), said current being provided by a current source external to said body (current generator 50 see Figure 1), applying a sensory stimulus to a patient (see Figure 5 and Column 7),

collecting a set of voltage measurements between selected ones of said plurality of electrodes while said current is passing between said at least one pair of electrodes (see Column 4, Lines 20-33); wherein the set of voltage measurements is collected over a predetermined measurement period (teaches the current applied for the voltage measurements),

wherein the results of the measurements are used to generate images of said specific part of the nervous system and information is output to a display, see column 4, lines 30-50.

John '372 teaches a method of monitoring a brain stimulus response during a predetermined measurement period that begins only after a time delay that is determined so as to monitor for a physiological response of a specific part of the nervous system based upon a neurological model following occurrence of the sensory stimulus (the evoked signal may be obtained during stimulation, beginning with the presentation of the stimuli or after a pre-selected delay, the delay selected for monitoring activity in the brain (a neurophysiologic model) the delay is set to collect data from the nervous system of interest, see [0034]).

Both Boone and John teach monitoring brain activity in response to a stimulus.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Boone to include initiating a measurement period a predetermined time after the stimulus as been applied as taught by John '372 in order to collect measurements during a period of interest by substituting

one art recognize measurement time frame for another to perform the function of recording stimulus responses.

John ‘335 teaches the method wherein, the collected measurements are compared with reference measurements for a specific region (the data is then analyzed and compared to a set of reference values, see [0011]) to determine normal or abnormal response of the nervous system (information can then be used to detect a normal (reference values) or abnormal (deviation from reference values) response to the stimulus to detect a physiological state, see [0017], which may then be outputted, see [0041]-[0042]).

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method taught by Boone to include comparing measurement values to a reference value for a specific region as taught by John ‘335, in order to showing the regions of “normal” and “abnormal“ responses, see John ‘335 [0041] and [0042].

Regarding claim 23, Boone in view of John ‘372 and John ‘335 further teaches the method according to claim 22, wherein the set of voltage measurements coolected over said measurement period is used to produce an image representing the distribution of impedance within the body (the data is stored to be processed into an image by reconstruction software, see Boone Figure 4, Column 4, Lines 33-46, a printer 49 may be used to print out a report on the patient. Preferably the printer is a color printer which is used to generate a topographic "heat scale" color-coded map of the patient's head

showing, by its colors, the patient's statistical "normal" and "abnormal" regions., see John '335 [0042]).

Regarding claim 26, Boone in view of John '372 and John '335 further teaches the method according to claim 22, wherein the applied sensory stimulus is a visual or an auditory stimulus (Visual stimulus see Boone Figure 1 and Figure 5).

Regarding claim 28, Boone teaches method according to claim 22, further comprising applying the sensory stimulus (see Figure 5 and Column 7).

Regarding claims 39 and 40, Boone in view of John '372 and John '335 teaches performing the method of claim 22 as set forth above.

Boone teaches a programmable control apparatus comprising a program to operate the data acquisition cycle using a processor, see Column 7, Lines 45-58) and

John '335 teaches a computer apparatus (Figure 1) comprising a non-transient computer readable medium a memory [data carrier carrying computer program code means to cause a computer to execute a procedure] (internal memory of approximately 100MB, see [0036]) and a processor (microprocessor, [0035]) for reading and executing instructions from said memory, wherein the memory comprises instructions, see [0018]).

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the apparatus taught by Boone to include a computing apparatus comprising memory and a processor for executing a method as taught by John '335, in order to perform the method of claim 22 above taught by Boone in view John '335 in order to generate a report showing the patients statistical "normal" and "abnormal" regions, see John '335 [0041] and [0042]. One of ordinary skill in the

art would recognize that the implementation of a method on a using instructions stored in memory, is a known well known means in the art for implementing a method.

Regarding claim 36, Boone teaches an apparatus for monitoring the response of a nervous system of a body to an applied sensory stimulus, said apparatus comprising:

means for applying a sensory stimulus to a body (pulse generator, 70, see Figure 1);

means for collecting a set of voltage measurements between selected electrodes in contact with said body while electrical current is being passed from an external source between other electrodes in contact with said body (amplifier 20 A/D converter 30, interface 40 and Computer 60), wherein the set of voltage measurements is collected over a predetermined measurement period, the predetermined measurement period (the measurements are collected over the measurement period shown in Figure 5) and means for comprising collected values (computer 60) which may comprise image analysis software,

means for outputting a result of said comparison (see column 4, lines 30-50).

Boone fails to teach the method wherein the measurement period begins after a time delay based upon a neuroloqical model following occurrence of the sensory stimulus, and means to compare the collected voltage measurements with reference measurements to determine normal or abnormal response of the nervous system

John '372 teaches a method of monitoring a brain stimulus response during a predetermined measurement period that begins after a time delay following the stimulus

said time delay is selected so as to montitor for a physiological response of a specific par to the nervous system based on a neurological model of the nervous sytem and the predetermined part of the nervous system for which a response is monitored (the evoked signal may be obtained during stimulation, beginning with the presentation of the stimuli or after a pre-selected delay, the delay selected for monitoring activity in the brain (a neurophysiologic model) the delay is set to collect data from the nervous system of interest, see [0034]).

Both Boone and John teach monitoring brain activity in response to a stimulus.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Boone to include inititating a measurement period a predetermined time after the stimulus as been applied as taught by John '372 in order to collect measurements during a period of interest by substituting one art recognize measurement time frame for another to perform the function of recording stimulus responses.

John '335 teaches an apparatus for monitoring a nervous system response comprising a means are provided (a computer system 40 comprising a processor 42 and memory 41 which can transmit and store data and a printer 49 to print normal and abnormal responses [0040]-[0042] the data is then analyzed and compared to a set of reference values, see [0011]) to compare the collected voltage measurements with reference measurements to determine normal (reference values) or abnormal (deviation from reference values) response to the stimulus to detect a physiological state, see [0017]).

Both Boone and John '335 teach an apparatus for monitoring a nervous system response to a stimulus.

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the apparatus taught by Yamazaki to include a means for comparing measured values to reference values as taught by John '335 in order to generate a report showing the patients statistical "normal" and "abnormal" regions, see John '335 [0041] and [0042].

Regarding claim 45, Boone discloses a method for monitoring the response of a nervous system of a body to a sensory stimulus (abstract), said method comprising:

Boone teaches providing plurality of electrodes on a surface of the body, (multiple electrodes E1-E16 are placed around the subjects head) wherein current is passed between selected areas of the surface of the body by passing current between at least one pair of electrodes of said plurality (current from the current generator is passed between E11 and E12, see Column 4, Lines 7-10), said current being provided by a current source external to said body (current generator 50 see Figure 1), applying a sensory stimulus to a patient (see Figure 5 and Column 7),

collecting a set of voltage measurements between selected ones of said plurality of electrodes while said current is passing between said at least one pair of electrodes (see Column 4, Lines 20-33); wherein the set of voltage measurements is collected over a predetermined measurement period (teaches the current applied for the voltage measurements).

wherein the results of the measurements are used to generate images of said specific part of the nervous system and information is output to a display, see column 4, lines 30-50.

John '372 teaches a method of monitoring a brain stimulus response during a predetermined measurement period that begins only after a time delay that is determined so as to monitor for a physiological response of a specific part of the nervous system based upon a neurological model following occurrence of the sensory stimulus (the evoked signal may be obtained during stimulation, beginning with the presentation of the stimuli or after a pre-selected delay, the delay selected for monitoring activity in the brain (a neurophysiologic model) the delay is set to collect data from the nervous system of interest, see [0034]).

Both Boone and John teach monitoring brain activity in response to a stimulus.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Boone to include initiating a measurement period a predetermined time after the stimulus as been applied as taught by John '372 in order to collect measurements during a period of interest by substituting one art recognize measurement time frame for another to perform the function of recording stimulus responses.

John '335 teaches the method wherein, the collected measurements are compared with reference measurements for a specific region (the data is then analyzed and compared to a set of reference values, see [0011]) to determine normal or abnormal response of the nervous system (information can then be used to detect a

normal (reference values) or abnormal (deviation from reference values) response to the stimulus to detect a physiological state, see [0017], which may then be outputted, see [0041]-[0042]).

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method taught by Boone to include comparing measurement values to a reference value for a specific region as taught by John ‘335, in order to showing the regions of “normal” and “abnormal“ responses, see John ‘335 [0041] and [0042].

Claims 29-31 and 41 rejected under 35 U.S.C. 103(a) as being unpatentable over Boone (US 5,919, 142) In view of John et al. (US 2004/0079372 A1, hereinafter referred to as John ‘372), John et al. (US 2002/0091335, hereinafter referred to as John ‘335) and Yamazaki et al. (US 5,638,825).

Regarding claim 29, Boone fails to explicitly disclose the method wherein the application of the stimulus is detected. Yamazaki teaches the method of applying a randomized stimulus, wherein when application of the stimulus is detected (the system measurement control section detects a stimulus is generated when the control section 20, sends a signal 202, to the measurement control section 13, after sending a signal 201 to energize the stimulator 11, Yamazaki Column 4, Lines 52-63) and said detection starts measurement of said time delay (the control section 13 receives the signal 202 and records after the stimulus form the flash apparatus, see Yamazaki Column 7, Lines 20-30).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Boone to include detecting the stimulus as taught by Yamazaki in order to provide a random stimulus which prevents a conditioned response and indicate to the measurement section to begin recoding.

Regarding claim 30, Yamazaki further teaches the method according to claim 29, wherein the sensory stimulus occurs spontaneously (the experimenter will input data into the control section 20 including a time interval 5+alpha wherein alpha is a random number between 0-1, which has not been predetermined, see Yamazaki Column 6, Line 40-45, thereby generating spontaneous stimulus for the user).

Regarding claim 31, Boone and Yamazaki further teach the method according to claim 30, wherein the sensory stimulus is a feature of an environment in which the body is located (Boone teaches the strobe being visual by the patient, Yamazaki, Figures 1 and 2 shows a stimulus device which provides a visual flash, the device and flash being a feature of the environment where the patients body is located)

Regarding claim 41, Boone discloses a method for monitoring the response of a nervous system of a body to a sensory stimulus (abstract), said method comprising:

Boone teaches providing plurality of electrodes on a surface of the body, (multiple electrodes E1-E16 are placed around the subjects head) wherein current is passed between selected areas of the surface of the body by passing current between at least one pair of electrodes of said plurality (current from the current generator is passed between E11 and E12, see Column 4, Lines 7-10), said current being provided

by a current source external to said body (current generator 50 see Figure 1), applying a sensory stimulus to a patient (see Figure 5 and Column 7),

collecting a set of voltage measurements between selected ones of said plurality of electrodes while said current is passing between said at least one pair of electrodes (see Column 4, Lines 20-33); wherein the set of voltage measurements is collected over a predetermined measurement period (teaches the current applied for the voltage measurements).

wherein the results of the measurements are used to generate images of said specific part of the nervous system and information is output to a display, see column 4, lines 30-50.

John '372 teaches a method of monitoring a brain stimulus response during a measurement period after a time delay after which the measurement period is initiated so as to monitor for a physiological response of a specific part of the nervous system following occurrence of the sensory stimulus (the evoked signal may be obtained during stimulation, beginning with the presentation of the stimuli or after a pre-selected delay, the delay selected for monitoring activity in the brain (a neurophysiologic model) the delay is set to collect data from the nervous system of interest, see [0034]).

Both Boone and John teach monitoring brain activity in response to a stimulus.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Boone to include initiating a measurement period a predetermined time after the stimulus as been applied as taught by John '372 in order to collect measurements during a period of interest by substituting

one art recognize measurement time frame for another to perform the function of recording stimulus responses.

John '335 teaches the method wherein, the collected measurements are compared with reference measurements for a specific region (the data is then analyzed and compared to a set of reference values, see [0011]) to determine normal or abnormal response of the nervous system (information can then be used to detect a normal (reference values) or abnormal (deviation from reference values) response to the stimulus to detect a physiological state, see [0017], which may then be outputted, see [0041]-[0042]).

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method taught by Boone to include comparing measurement values to a reference value for a specific region as taught by John '335, in order to showing the regions of "normal" and "abnormal" responses, see John '335 [0041] and [0042].

Yamazaki teaches a user input time delay wherein the user inputs various experimental features to setup the experiment procedures (see Column 6, Lines 28-50).

Therefore it would have been obvious to one of ordinary skill in the art to modify the delay circuit taught by Boone in view of John '372 to include a user input as taught by Yamazaki in order to provide a variable circuit that can be adjusted by the experimenter depending on the desired operation of the device.

Claims 32, 33, 34, 37 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boone (US 5,919, 142) In view of John et al. (US 2004/0079372 A1, hereinafter referred to as John '372).

Regarding claims 32, 47 and 49, Boone discloses a method and apparatus for monitoring the response of a nervous system of a body to a sensory stimulus (abstract), said method/apparatus comprising:

a means for applying or detecting the occurrence of a sensory stimulus to the nervous system of a living body (Boone teaches applying a sensor stimulus to generate an evoked potential, see column 4, lines 2-67 and Figures 1-4),

identify a predetermined part of a nervous system of a body, (brain 10, see Figure 1), Boone teaches providing plurality of electrodes on a surface of the body, (multiple electrodes E1-E16 are placed around the subjects head) wherein current is passed between selected areas on the surface of the body by passing current between at least one pair of electrodes of said plurality (current from the current generator is passed between E11 and E12, see Column 4, Lines 7-10), said current being provided by a current source external to said body (current generator 50 see Figure 1),

collecting a set of voltage measurements between selected ones of said plurality of electrodes co-currently while said current is passing between said at least one pair of electrodes (see Column 4, Lines 20-33); wherein the set of voltage measurements is collected over a predetermined measurement period (teaches the current applied for the voltage measurements),

Boone discloses a means for injecting electrical current form an extnal source and concurrently collecting voltage measurements form the surface of the body, see sections above),

outputting a result based on said set of voltage measurements, (Boone teaches the method wherein the results of the measurements are used to generate images of said specific part of the nervous system and information is output to a display, see column 4, lines 30-50).

John '372 teaches a method and apparatus of monitoring a brain stimulus response over a measurement period comprising a means for establishing a time delay (a multiplexer programmed to obtain a signal after a preselected delay, see [0034]) which beings after a time delay following the sensory stimulus, said time delay is selected so as to monitor for a physiological response of a specific part of the nervous system based on a neurological model of the nervous system and the predetermined part of the nervous system for which a response is monitored (the evoked signal may be obtained during stimulation, beginning with the presentation of the stimuli or after a pre-selected delay, the delay selected for monitoring activity in the brain, (a neurophysiologic model) the delay is set to collect data from the nervous system of interest, if the nerophysiological aspects of the brain are not taken into account the data obtained after the delay will not be of interest to the results desired, in other words, the system/method, including the delay, is designed to obtain information Of interest from the brain, with the neurophysiological features of the brain being taken into account, see [0034]).

Both Boone and John '372 teach monitoring brain activity in response to a stimulus.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method/apparatus taught by Boone to include inititating a measurement period a predetermined time after the stimulus as been applied as taught by John '372 in order to collect measurements during a period of interest by substituting one art recognize measurement time frame for another to perform the function of recording stimulus responses.

John '335 teaches the method wherein, the collected measurements are compared with reference measurements for a specific region (the data is then analyzed and compared to a set of reference values, see [0011]) to determine normal or abnormal response of the nervous system (information can then be used to detect a normal (reference values) or abnormal (deviation from reference values) response to the stimulus to detect a physiological state, see [0017], which may then be outputted, see [0041]-[0042]).

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method taught by Boone to include comparing measurement values to a reference value for a specific region as taught by John '335, in order to showing the regions of "normal" and "abnormal" responses, see John '335 [0041] and [0042].

Regarding claim 33, Boone in view of John '335 teaches the method wherein, the collected measurements are compared with reference measurements (the data is

then analyzed and compared to a set of reference values, see [0011]) to determine normal or abnormal response of the nervous system (information can then be used to detect a normal (reference values) or abnormal (deviation from reference values) response to the stimulus to detect a physiological state, see [0017]).

Regarding claim 34, Boone further teaches the method according to claim 32, further comprising applying the sensory stimulus (Visual stimulus see Boone Figure 1 and Figure 5).

Regarding claim 37, Boone teaches an apparatus for monitoring the response of a predetermined part of a nervous system of a body to an applied sensory stimulus, said apparatus comprising:

a plurality of electrodes for attaching to a surface of the body (E1-E16), said plurality of electrodes being arranged to pass current between selected areas on the surface of the body by passing current between at least one pair of electrodes of said plurality of electrodes (E12 and E11), said current being provided by a current source external to said body (current generator 50); means for applying the sensory stimulus (Pulse generator), and means for collecting a set of voltage measurements between selected ones of said electrodes while said current is being passed between said at least one pair of electrodes (amplifier 20, converter 30 and interface 40),
wherein the set of voltage measurements is collected over a predetermined measurement period (measurement period of 100ms, see Claim 22 above),

wherein the results of the measurements are used to generate images of said specific part of the nervous system and information is output to a display, see column 4, lines 30-50,

outputting a result based on said set of voltage measurements, (Boone teaches the method wherein the results of the measurements are used to generate images of said specific part of the nervous system and information is output to a display, see column 4, lines 30-50).

Boone fails to teach the apparatus wherein the predetermined measurement period is initiated after a predetermined delay following occurrence of the sensory stimulus, and said predetermined time is selected on the basis of a neurological model of the nervous and the predetermined part of the nervous system for which a response is monitored.

John '372 teaches a method of monitoring a brain stimulus response over a measurement period which beings after a time delay following the sensory stimulus, said time delay is selected so as to monitor for a physiological response of a specific part of the nervous system based on a neurological model of the nervous system and the predetermined part of the nervous system for which a response is monitored (the evoked signal may be obtained during stimulation, beginning with the presentation of the stimuli or after a pre-selected delay, the delay selected for monitoring activity in the brain, (a neurophysiologic model) the delay is set to collect data from the nervous system of interest, if the nerophysiological aspects of the brain are not taken into account the data obtained after the delay will not be of interest to the results desired, in

other words, the system/method, including the delay, is designed to obtain information Of interest from the brain, with the neurophysiological features of the brain being taken into account).

Both Boone and John ‘372 teach monitoring brain activity in response to a stimulus.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Boone to include inititating a measurement period a predetermined time after the stimulus as been applied as taught by John ‘372 in order to collect measurements during a period of interest by substituting one art recognize measurement time frame for another to perform the function of recording stimulus responses.

Regarding claim 44, Boone discloses a method for monitoring the response of a nervous system of a body to a sensory stimulus (abstract), said method comprising:

Boone teaches providing plurality of electrodes on a surface of the body, (multiple electrodes E1-E16 are placed around the subjects head) wherein current is passed between selected areas of the surface of the body by passing current between at least one pair of electrodes of said plurality (current from the current generator is passed between E11 and E12, see Column 4, Lines 7-10), said current being provided by a current source external to said body (current generator 50 see Figure 1), applying a sensory stimulus to a patient (see Figure 5 and Column 7),

collecting a set of voltage measurements between selected ones of said plurality of electrodes while said current is passing between said at least one pair of electrodes

(see Column 4, Lines 20-33); wherein the set of voltage measurements is collected over a predetermined measurement period (teaches the current applied for the voltage measurements).

wherein the results of the measurements are used to generate images of said specific part of the nervous system and information is output to a display, see column 4, lines 30-50.

John '372 teaches a method of monitoring a brain stimulus response during a predetermined measurement period that begins only after a time delay that is determined so as to monitor for a physiological response of a specific part of the nervous system based upon a neurological model following occurrence of the sensory stimulus (the evoked signal may be obtained during stimulation, beginning with the presentation of the stimuli or after a pre-selected delay, the delay selected for monitoring activity in the brain (a neurophysiologic model) the delay is set to collect data from the nervous system of interest, see [0034]).

Both Boone and John teach monitoring brain activity in response to a stimulus.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Boone to include initiating a measurement period a predetermined time after the stimulus as been applied as taught by John '372 in order to collect measurements during a period of interest by substituting one art recognize measurement time frame for another to perform the function of recording stimulus responses.

Regarding claims 48 and 50, Boone in view of John teaches the method/apparatus of claims 47 and 49 above as set forth above, wherein step (b) comprises an electrical impedance tomography (EIT) process which is triggered to begin after said time delay and wherein step (C) comprises display of at least one EIT image, (Boone teaches the measurement process comprising performing an EIT measurements and generating an image, see Column 4, John teaches the fundamental concept of initiating a measurement process a delay after the stimulus has been applied).

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boone (US 5,919, 142) In view of John et al. (US 2004/0079372 A1, hereinafter referred to as John '372) and in view of Polydorides et al. ("Krylov Subspace Iterative Techniques: on Detection of Brain Activity with Electrical Impedance Tomography," IEEE Transactions on Medical Imaging, Vol. 21 No. 6, June 2002).

Regarding claim 35, Boone teaches placement of the electrodes to detect brain activity, but fails to explicitly teach the method wherein said regions and/or areas are selected on the basis of a neurological model of the nervous system and the applied sensory stimulus such that sensitivity of the derived impedance measurements to changes in the predetermined part of the nervous system is maximized (One of ordinary skill in the art would recognize that the placement of the electrodes near the visual cortex region of the brain will provide a better indication of response (maximize the sensitivity) to a visual stimulus than placing the electrodes distally from the region)

Polydorides teaches a method of detecting brain activity particularly with response to visually stimulation (I. Introduction Paragraphs 1 and 2) comprising passing current between selected regions of a surface of the body, and collecting a set of voltage measurements between selected areas on the surface of the body whilst current is being passed (see I. Introduction Paragraph 1), wherein the said regions and/or areas are selected on the basis of a neurological model of the nervous system and the applied stimulus such that sensitivity of the derived impedance measurements to changes in the predetermined part of the nervous system is enhanced (Polydorides also teaches the placement of electrode patters are deliberately placed where the targeted effect was “expected” to occur in order to enhance the system’s sensitivity in that particular region, see Page 601, Column 1, Paragraph 2).

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method taught by Boone clude injecting currents and collecting voltages as taught by Polydorides in order to position the elctrodes where are response is expected to occur to increase sensitivity.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boone (US 5,919, 142) In view of John et al. (US 2004/0079372 A1, hereinafter referred to as John ‘372) and John ‘335 et al. (US 2002/0091335) and in further view of Vauhkonen et al. (*“A Kalman Filter Approach to Track Fast Impedance Changes in Electrical*

Impedance Tomography," IEEE Transactions on Biomedical Engineering, Vol 45, NO. 4, April 1998).

Boone in view of John '372 and John '335 teaches a method of recording voltages to make an impedance image, see John '335 [0042].

Boone in view of John '372 and John '335 fails teach a method wherein the measured voltages are filtered using a Kalman filter.

Vauhkonen teaches a method of making an image using voltage measurements wherein the measurements are filtered using a Kalman filter, see Abstract.

Boone, John '335 and Vauhkonen teach methods for monitoring a nervous system response to a stimulus.

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method taught by Boone/John '335 to include filtering measurements using a Kalman filter as taught by Vauhkonen in order track fast impedance changes in the impedance distribution, see Vauhkonen Abstract.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boone (US 5,919, 142) In view of John et al. (US 2004/0079372 A1, hereinafter referred to as John '372) and in further view of Maddess et al. (US 2003/0163060 A1).

Regarding claim 46, Boone discloses a method for monitoring the response of a nervous system of a body to a sensory stimulus (abstract), said method comprising:

Boone teaches providing plurality of electrodes on a surface of the body, (multiple electrodes E1-E16 are placed around the subjects head) wherein current is

passed between selected areas of the surface of the body by passing current between at least one pair of electrodes of said plurality (current from the current generator is passed between E11 and E12, see Column 4, Lines 7-10), said current being provided by a current source external to said body (current generator 50 see Figure 1), applying a sensory stimulus to a patient (see Figure 5 and Column 7),

collecting a set of voltage measurements between selected ones of said plurality of electrodes while said current is passing between said at least one pair of electrodes (see Column 4, Lines 20-33); wherein the set of voltage measurements is collected over a predetermined measurement period (teaches the current applied for the voltage measurements),

wherein the results of the measurements are used to generate images of said specific part of the nervous system and information is output to a display, see column 4, lines 30-50.

John '372 teaches a method of monitoring a brain stimulus response during a predetermined measurement period that begins only after a time delay that is determined so as to monitor for a physiological response of a specific part of the nervous system based upon a neurological model following occurrence of the sensory stimulus (the evoked signal may be obtained during stimulation, beginning with the presentation of the stimuli or after a pre-selected delay, the delay selected for monitoring activity in the brain (a neurophysiologic model) the delay is set to collect data from the nervous system of interest, see [0034]).

Both Boone and John teach monitoring brain activity in response to a stimulus.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method taught by Boone to include initiating a measurement period a predetermined time after the stimulus as been applied as taught by John '372 in order to collect measurements during a period of interest by substituting one art recognize measurement time frame for another to perform the function of recording stimulus responses.

Boone teaches method of monitoring a visual stimulus response of the brain wherein electrodes are positioned in the plane of the body to be investigated, wherein images of the brain are generated along the cross section of the subjects brains in which the electrodes lie, see Background and column 4, lines 30-47. However Boone is silent regarding specifically monitoring the response of the lateral geniculate.

Maddess teaches a method of monitoring a nervous system response to a visual stimulus wherein the lateral geniculate nucleus is a visual processing center for the brain which receives inputs from the optical fibers, see [0054] and is a region of interest when monitoring responses to visual stimuli.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the method of monitoring a patients nervous system in response to a visual stimulus taught by Boone in view of John '372 to include monitoring the lateral geniculate nucleus as taught by Maddess in order to monitor a region of the brain involved with processing visual stimuli, wherein measurements are taken after a pre-selected delay to obtain measurements in the lateral geniculate

nucleus ensuring that the delay is selected such that measurements of interest are obtained.

Allowable Subject Matter

Claims 24, 25 and 43 are allowed.

The prior art fails to teach or suggest a method of monitoring the response of a nervous system to an applied sensory stimulus comprising applying a second stimulus and recording measurements after a different second predetermined delay as set forth in claims 24 and 43.

Response to Arguments

Applicant's arguments, see Declaration, filed 12/8/2010 and 2/11/2011 have been fully considered and are not found to be persuasive.

The claims recite the limitation of a measurement period beginning after a predetermined delay which is selected based on a physiological model, wherein the measurement period includes injection of current form a current source.

Boone the primary reference teaches measuring an evoked response of the nervous system wherein during measurement current is injected during the measurement period. The secondary reference John '372 which is a method of monitoring an evoked response of the nervous system is relied upon to teach the limitation of the measurement period beginning a specific delay after the stimulus is

applied. The system of John '372 is designed with an understanding of the nervous system in mind (a neurophysiological model) and delay including the other components have to be selected with this model in mind otherwise the data gathered will not be relevant.

Thus the combination teaches the limitation of beginning a measurement period comprising current injection a predetermined delay based upon a neurophysiological model after the stimulus is applied, as currently broadly claimed in the non-allowed independent claims.

The Examiner notes that the disclosure recites specific delays which result in certain outcomes which are not taught by combination of Boone and John '372, but are not currently claimed.

In Regards to the Applicant's Arguments filed 2/11/2011, the Applicant argues that because the Boone and John '372 are drawn to two different specific technologies (active and passive monitoring of evoked potentials), they are non-analogues and cannot be combined, and because delay is not found in art amount of art in active monitoring (see Applicant's arguments), suggest the non-obviousness of the method comprising the use of the specific delay based upon the neurological model.

The Examiner Disagrees.

In response to applicant's argument that Boone and John '372 are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the

claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Boone and John '372 are monitoring a evoked response of the nervous system in response to a stimuli, and a brain response being monitored after a certain delay with a passive system can be monitored with an active system.

Regarding the Applicant's declaration filed 12/08/2010, the limitation of the references teaching the delay based on a neurophysiologic model is addressed in the remarks above. The Applicant further argues that John '372 teaches continuous monitoring and therefore cannot teach a delay. John '372 expressly discloses a delay in paragraphs [0054] as cited in the office action above. There examiner notes that continuous monitoring can broadly be interpreted to mean taking measurements over an extending period of time, i.e. monitoring a patients vital signs every 10min for 24 hours.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is (571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736